UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,068	08/01/2001	Eckhard Wolf	50125/015002	4409

21559 7590 11/03/2003

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,068	WOLF ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed February 25, 2003. Currently, claims 1-79 are pending.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 12-13, 15-16, 20-21, 33-34, drawn to a G-protein-coupled receptor-polypeptide, classified in 530, subclass 350^{+}.

II. Claims 3-6, 12-17, 20-21, 33-34, drawn to nucleic acid, a cell and a method of producing a polypeptide, classified in 536, subclass 23.1, 435/69.1, 435/320.1, 435/325, for example.

III. Claims 7, 8 and 18, drawn to a transgenic embryonic non-human stem cell, a transgenic non-human mammal, and a method of making, classified in class 800, subclass 13.

IV. Claims 9, 12-13, 15-16, 19-21 and 33-34, drawn to an antibody or antibody fragment and a method of making, classified in 424, subclass 130.1^{+}.

V. Claims 10, 11, 22, 25-27, 29-30, 31-34, drawn to a test for identification of a pharmacologically active substance, which contains at least one G-protein-coupled receptor-polypeptide, classified in class 530, subclass 350+.

VI. Claims 10, 11, 22, 25-27, 29-30, 31-34, drawn to a test for identification of a pharmacologically active substance, which contains at least one nucleic acid encoding the G-protein-coupled receptor-polypeptide, classified in class 435, subclass 6.

VII. Claims 10, 11, 22, 25-27, 29-30, 31-34, drawn to a test for identification of a pharmacologically active substance, which contains at least one antibody directed against the G-protein-coupled receptor-polypeptide, classified in class 435, subclass 7.1.

VIII. Claims 10, 11, 22, 25-27, 29-30, 31-34, drawn to a test for identification of a pharmacologically active substance, which contains at least one cell expressing the G-protein-coupled receptor-polypeptide, classified in class 435, subclass 4.

IX. Claims 10, 11, 22, 25-27, 29-30, 31-34, drawn to a test for identification of a pharmacologically active substance, which contains at least one transgenic non-human mammal containing the nucleic acid encoding the G-protein-coupled receptor-polypeptide, classified in class 800, subclass 3.

X. Claims 23-24, 28-34,drawn to method for analysis or diagnosis of disease using an array comprising at least one G-protein-coupled receptor-polypeptide, classified in class 435, subclass 7.1.

XI. Claims 23-24, 28-79 drawn to method for analysis or diagnosis of disease using an array comprising at least one nucleic acid encoding the G-protein-coupled receptor-polypeptide, classified in class 435, subclass 6.

XII. Claims 23-24, 28-34,drawn to method for analysis or diagnosis of disease using an array comprising at least one antibody directed against the G-protein-coupled receptor-polypeptide, classified in class 435, subclass 7.1+.

XIII. Claims 23-24, 28-34,drawn to method for analysis or diagnosis of disease using an array comprising at least one cell expressing the G-protein-coupled receptor-polypeptide, classified in class 435, subclass 4.

XIV. Claims 23-24, 28-34,drawn to method for analysis or diagnosis of disease using an array comprising at least one transgenic non-human mammal containing the nucleic acid encoding the G-protein-coupled receptor-polypeptide, and a method of using, classified in class 800, subclass 3.

3. It is noted that several of the claims appear in more than one group. The claims which appear in more than one group will only be examined to the extent that they read on the elected subject matter. Prior to allowance, the non-elected subject matter must be cancelled from the claim.

4. The inventions are distinct, each from the other because:

Groups I-IV are distinct from each other because they are drawn to compositions with different classification: polypeptide, nucleic acid, non-human transgenic animal and antibody, respectively. These compositions have different chemical structures, physical

properties and biological functions, and requiring separate search. Search for polypeptide does not require search for nucleic acid, non-human transgenic animal, or antibody, search for nucleic acid does not require search for polypeptide, non-human transgenic animal, or antibody, and search for non-human transgenic animal does not require search for, polypeptide, nucleic acid, or antibody. Since the classification for each is different, the search for each group would not be coextensive. They are not obvious variants and deemed patentably distinct.

Groups V-XIV are distinct from each other because they are drawn to methods using different compositions for test, having different chemical structures, physical properties and biological functions, and requiring separate search, they are: polypeptide, nucleic acid, antibody, cell and non-human transgenic mammal, respectively. They are methods that differ at least in reagents used, doses and schedules used, response variables, and criteria of success. Since the classification for each is different, the search for each group would not be coextensive. They are patentably distinct.

Inventions I-IV and (V-XIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids may be used in methods of purification, aptamer screening methods, hybridization assays and antisense methods. The polypeptides may be used to raise antibodies.

The antibodies may be used to treat diseases. Transgenic animals may be used to raise various antibodies aside from a G-protein-coupled receptor polypeptide of SEQ ID NO: 1 or 3.

Restriction Requirement Applicable to All Groups:

5. The claims are drawn to two different genes, namely SW1368 and SW1695, as seen in Figure 4. Each of these genes has the human and mouse homologue. The genes are identified by different sequences. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. A restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequences (See MPEP 803.04).

The claims contains 2 individual, independent and distinct nucleotide sequences in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. 121 as outlined in 1192 O.G. 68 (November 19, 1996).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are

presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Applicant is required to select one of the individual sequences for examination. The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Should applicant traverse on the ground that the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, because of their recognized divergent subject matter, and the search required for any group is not required for remaining groups, restriction for examination purposes as indicated is proper.

7. A telephone call was made to Karen Elbing on October 28, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made. Karen Elbing returned the call on October 31, 2003 and indicated that it may

take a few days for a response. The examiner indicated that she would send the restriction out in writing.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).)

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

G. Goldberg
Oct. 31, 2003